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Biotechnology: Concepts and Issues for Consideration in Preparation of a Framework Legal Instrument For the Conservation of Biological Diversity

Executive Summary

INTRODUCTION

1. The study sets out the key issues and concepts related to biotechnology that must be addressed in the development of a framework legal instrument on biological diversity.

II. WHAT IS BIOTECHNOLOGY?

2. The UNIDO/WHO/UNEP Working Group on Biotechnology Safety defined biotechnology as the application of biological systems and organisms to scientific, industrial, agricultural and environmental processes and uses. "Organisms" includes plants, animals and microbes that occur naturally or that have been genetically modified.

III. BIOTECHNOLOGY AND BIOLOGICAL DIVERSITY

3. The relationship between biotechnology and biological diversity is mutually dependent. Biotechnology has much to offer to biological diversity conservation. It will lead to new and improved methods of preservation of genetic resources and speed the evaluation of germplasm for specific traits.

4. Biological diversity is the foundation from which biotechnology develops. The projected loss in biological diversity could severely erode the genetic base required for the continued improvement and maintenance of currently utilized species and limit the potential to develop new ones.

IV. ISSUES FOR CONSIDERATION

A. Biotechnology Research and Development - Socio-economic Impacts

5. The development of biotechnology has historically been focused on the needs and priorities of industrialized societies. However, biotechnological requirements and opportunities will not be the same in agrarian as in industrial societies. The framework legal instrument on the conservation of biological diversity should promote development and application of biotechnological solutions which take into consideration the particular ecosystems, crops, cultural practices and needs of developing as well as industrialized societies.

6. The "Biotechnological Revolution" is largely a product of the private sector. The growing relationship between universities and corporations has long-term implications for developing countries, including the direction of research, public accountability, intellectual secrecy and creativity. Most biotechnology research in industrialized countries is focused on specific problems in those countries or on products with high market potential. Funding is devoted to areas which are important, but which might not be the priority areas for developing countries.

7. The direction of much research in industrialized countries is aimed at reducing dependence on imported raw materials. For many of these commodities that are presently grown in developing countries, particularly the high-value products, there is the threat of displacement or of over-production.

8. Developing countries will require substantial public sector investments by national governments, bilateral donors and international organizations in order to mitigate the negative impacts of biotechnology.

9. The issues are: (i) what is industry's impact on the biotechnology research agenda and how can it be mitigated? (ii) what is the most effective way to facilitate the development of modern biotechnology and its implication to the problems that are of particular concern of developing countries? (iii) what is the potential impact of product displacement and over-production?

B. Biotechnology Transfer

10. The increasing dominance of the private sector in biotechnology also has implications for the issue of access to advances in science and technology by developing countries.

11. Increased corporate support for university research has led to the restriction of research findings as trade secrets. Research results no longer form part of the body of scientific and technical knowledge accessible to all as public goods.

12. Co-operation with reciprocal benefits must be established between developing countries and industrialized countries in order to mitigate the effects of technical secrecy laws and harsh competition for the appropriation of germplasm.

13. The industrialized countries most active in agricultural biotechnology depend heavily on the developing countries for the germplasm they need, yet the developing countries have not benefited proportionately from the resulting flow of germplasm. The biotechnology industry's stake in the conservation of genetic diversity should not be underestimated.

14. The issues are: (i) how to increase developing countries' access to biotechnology on equitable terms? (ii) how to help developing countries avoid or diminish external dependencies in utilizing biotechnology? (iii) how can mutually beneficial transfer arrangements be facilitated?

C. Biotechnology and Sustainable Development

15. Biotechnologies have considerable potential in the field of sustainable resource management. The development and use of biotechnologies in this field need to be encouraged to contribute to solving the problems facing developing countries.

16. Consideration should be given to how contacts between the bio-industry and the organizations that promote sustainable development can be encouraged.

17. The proposed framework legal instrument could provide for consideration of an international body or mechanism to play a "brokering" role for governments of developing countries that are interested in sustainable development and in building up their national biotechnology programmes and the bio-industries in industrialized countries.

18. The privatization that has occured with the development of biotechnologies perpetuates technological dependence. Those who have competitive advantage in scientific and technological knowledge have the potential to shape the global agricultural sector.

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19. The issues are: (i) should public biotechnology research centres be strengthened or established? (ii) how should capacity to apply some of the emerging biotechnologies be strengthened? (iii) how can local groups share the benefits and burdens resulting from the adoption of biotechnology more equitably? (iv) what is the best mechanism for assisting developing countries in identifying biotechnological processes which can have socio-economic benefits? (v) what is the most effective way to train personnel in biotechnology and its relationship to sustainable development?

D. Gene Banks

20. Gene banks are subject of controversy because of their control of genetic material.

21. Information pertaining to the genetic material in private collections is not as easily available as information on material in public sector gene banks. Genetic resources collected by seed companies are not likely to be freely exchanged. These resources may also be part of specific breeding programmes or research and may be considered trade secrets.

22. Many developing countries are faced with physical and economic constraints and difficulties that can hamper their ex-situ conservation efforts.

23. The high performance of developing countries' gene banks supports the notion of strengthening the capacity of developing countries to conserve their resources. The proximity of these gene banks to the centres of diversity gives them comparative advantage over the banks in industrialized countries. An effective training programme is needed to equip the developing nations with the technical ability to manage gene banks effectively and at all levels: regional, national and local.

24. The issues are: (i) the precise scope and implication of ownership and access must be defined; (ii) the equitable management and administration of gene banks must be discussed; (iii) should provision be made for the establishment of national or regional gene banks in developing countries?

E. Environmental Impacts

25. Since biotechnology's emergence, the range of applications and techniques has expanded and so have the potential risks. The intentional release of genetically manipulated organisms into the environment poses major challenges. It is difficult to introduce regulations in a new field, because of the absence of prior experience.

26. Extensive regulation may stall research, yet the uncertain outcome of such research may have far-reaching consequences. For example, the potential implications of the introduction of new life forms cannot be predicted.

27. Risk perception changes with the amount of information available to the public. The fact that most of the biotechnology innovations are governed by secrecy and intellectual property laws limits the amount of information available to the public. This in turn reduces the capacity of the public to make reasonable decisions about the risks involved.

28. The internationl legal instrument on the conservation of biological diversity should contain provisions on the need for strict regulation, on an international and national basis, of intentional or accidental release into the environment of genetically engineered organisms or alien species, and provisions on the establishment of testing procedures.

29. The issues are: (i) is a biotechnology code of conduct desirable? (ii) how should release of genetically-engineered organisms be regulated? (iii) what form should guidelines for biotechnology environmental impact assessment take?

V. CONCLUSION

30. The emerging techniques in biotechnology offer both prospects and problems for the conservation of global biological diversity. The issues raised by biotechnology are of great concern to both developing and developed countries and need to be the subject of careful analysis, elaboration and discussion between all the parties involved, in order to arrive at a mutual agreement on these issues.

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ONGOING DISCUSSIONS ON INTELLECTUAL PROPERTY RIGHTS IN URUGUAY ROUND OF GATT NEGOTIATIONS

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1. Global environmental problems could perhaps be solved by appropriate counterstrategies. Such strategies imply the necessity to ease the conditions for the developing countries' access to capital resources, technologies and know how, and the conditions under which these can be transferred to developing countries. From that angle, one may also assess the eventual future outcome of the Uruguay Round of Multilateral Trade Negotiations including those on trade-related aspects of intellectual property rights (TRIPs), within the framework of the General Agreement on Tariffs and Trade (GATT).

2. Intellectual property rights (IPRS) are at the core of every technology, including environment-related technologies. In the Uruguay negotiations there is a clear conflict of interests between technology-rich and technology-poor countries. The former group are interested in increased protection for IPRs, while the latter do not want this increased.

3. During the negotiations, specific comments were made about standards and principles governing the availability, scope, and application of trade-related IPR's, calling for internationally agreed minimum standards and principles for their protection. The effect of such a proposal would be an increase in international protection for IPRs. It was suggested that the authority to control imports and exports of goods that infringe IPRs be extended to customs authorities and that there be a curb on alleged infringements stemming from the tendency for developing countries to adopt a process patent system instead of a product patent system. Safeguards on the acquisition and maintenance of IPRs were to be upgraded by strengthening GATT-based rules and principles. Effective action at borders by customs authorities against infringements, as well as remedies against domestic production and sale of counterfeit goods were called for.

4. The specifically environment-related technologies or IPRs were not discussed. What gives rise to special concern is the role of developing countries in world development and global environmental protection. For those countries to choose ecologically sound development means additional costs in the short term. Moreover, with the advances in biotechnologies, it had been realized that genetic resources would be one of the most important elements for future world development. Nowadays genetic resources are treated as public goods, without real commercial value. They may acquire potential economic value, provided that gene-rich countries, which are mainly developing countries, have access to technologies that will enable them to commercialize this resource. The greater the probability of access to such technologies at a lower cost, the better the chances of realizing the economic value of countering the diminution of biological diversity.

5. As far as environment-related technologies are concerned, the likely outcome of the Uruguay Round on TRIPs will be to increase the cost of the access to and transfer of such technologies, if they are to be appropriate on a commercial basis. The strengthened monopolistic position of the IPRs' owner will enable an increase in the price of environment-related technologies and limit the possibility of acquiring the technology from secondary sources. Moreover, imitation will be difficult, as it infringes IPRs and will be subjected to greater international control. Measures against trade in counterfeit goods may decrease the opportunities for international trade in

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products that have been developed through indigenous research and development activities. This, in turn, may restric the economically viable scale of production and increase the costs per unit. In addition, some countries mayhave doubts about using environmentally sound technologies that will increase the unit cost of production and further erode the competitive edge of the producer.

6. The above-mentioned practices, if induced by the eventual final outcome of the GATT negotiations on TRIPs, may decrease the developing countries' interest in preservation of biological diversity.